FINDING OF NO SIGNIFICANT IMPACT
AND
DECISION
FOR
2004 SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT
ORAL VACCINATION
TO CONTROL SPECIFIC RABIES VIRUS VARIANTS
IN
RACCOONS, GRAY FOXES, AND COYOTES
IN THE UNITED STATES

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Wildlife Services (APHIS-WS) program completed an environmental assessment (EA) and Decision/Finding of No Significant Impact (FONSI) (USDA 2001) on July 30, 2001 (66 FR 45835-45836, August 30, 2001) that analyzed the potential environmental effects of a proposal to continue and expand the involvement of the APHIS-WS program in oral rabies vaccination (ORV) programs in a number of states. Since that time, APHIS-WS determined the need to expand the ORV program to include the states of Tennessee and Kentucky to effectively stop the westward spread of raccoon rabies. A supplemental Decision/FONSI (USDA 2002) was published in the Federal Register (67 FR 44797-44798, July 5, 2002) to document the potential effects of this expanding program. Next, a supplemental EA (USDA 2003) was prepared as a result of the need to further expand the program to include the states of Georgia and Maine to effectively prevent the westward and northward spread of the rabies virus across the U.S. and into Canada. A third Decision/FONSI was published in the Federal Register (68 FR 38669-38670, July 30, 2003) to record the potential effects of this expanding program. APHIS-WS, in cooperation with the USDA-Forest Service (USFS), prepared an EA (USDA 2004b) to expand the ORV program to combat the raccoon strain of the rabies virus on National Forest System lands (excluding Wilderness Areas) in the eastern U.S. A Decision/FONSI was published in the Federal Register (69 FR 7904-7905, February, 20, 2004) to record the potential effects of this expanding program.

In 2004, APHIS-WS determined that further NEPA documentation was needed as a result of: 1) increased federal involvement in ORV programs in recent years; 2) the current proposal to continue or expand federal involvement in such programs in additional states; and 3) the need for expanded monitoring and surveillance in the event contingency actions must be implemented. Thus, APHIS-WS prepared a supplemental EA (USDA 2004a) to include 26 states (Alabama, Connecticut, Delaware, Florida, Georgia, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, and West Virginia) and the District of Columbia in the proposed action. Another Decision/FONSI was published in the Federal Register (69 FR 56992-56993, September 23, 2004) to record the potential effects of this expanding program. In response to the expanded program area, APHIS-WS also supplemented the EA (USDA 2006a) covering ORV program activities on National Forest System lands (excluding Wilderness Areas) in the eastern U.S. to include national forests located in states that were not previously covered. A Decision/FONSI was published in the Federal Register (70 FR 72977-72978, December 8, 2005) to document potential effects of the further expanded program.

The purpose of this new 2007 Decision/FONSI is to clarify the term "contingency actions" which is used in the 2004 supplemental EA. Clarification should facilitate planning and interagency coordination in the event of rabies outbreaks and clearly communicate to the public the actions involved in the ORV program. In addition, a type of contingency action called trap-vaccinate-release (TVR) is analyzed in this Decision document as it was not analyzed as part of the proposed action in the 2004 supplemental EA. Analysis of TVR in this document does not involve any substantially new information and does not raise or create any new substantive issues or circumstances and, thus, APHIS-WS has determined that there is no need to supplement the 2004 EA with this analysis. This new 2007 Decision/FONSI is updating and replacing the previous Decision/FONSI, dated September 9, 2004, for the 2004 supplemental EA.

2004 Supplemental EA Information

Summary

The supplemental EA (USDA 2004a) documents the analysis of the potential environmental effects of a proposal to continue and expand the involvement of the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Wildlife Services (APHIS-WS) program in oral rabies vaccination (ORV) programs in 26 states and the District of Columbia. The states where APHIS-WS involvement will be continued or expanded include: Alabama, Connecticut, Delaware, Florida, Georgia, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, and West Virginia. The programs' primary goals are to stop the spread of specific raccoon (eastern states), gray fox (Texas) and coyote (Texas) rabies variants or "strains" of the rabies virus. If not stopped, these strains could potentially spread into much broader areas of the U.S. and Canada and cause substantial increases in public and domestic animal health costs because of increased rabies exposures.

The oral rabies vaccine used in these programs is the recombinant vaccinia-rabies glycoprotein (RABORAL V-RG® MERIAL, Inc.) vaccine currently licensed for use in raccoons and coyotes in the U.S. and Canada (although it is only being used for raccoons in Canada, as canine rabies does not occur in coyotes in Canada) and approved for experimental use in gray fox in Texas. It has been used extensively and successfully in Europe to combat fox rabies. This vaccine is contained in baits which are distributed by aircraft and by ground placement and then located and consumed by the target species. The vaccine has been found to be safe for use in a number of animal species.

The proposed action involves the use of federal funds by APHIS-WS to purchase ORV baits and cooperate with programs in the aforementioned states in the distribution of such baits to create zones of vaccinated target species that then serve as barriers to further advancement of the particular rabies virus variants. ORV baits may also be used in other areas where the particular rabies virus variants are known to occur with the goal of eliminating those variants from such areas. The proposed action also includes APHIS-WS assistance in monitoring and surveillance activities involving the capture and release or lethal collection of the targeted animal species in the aforementioned states to take biological samples for testing to determine the effectiveness of the ORV programs. APHIS-WS may also assist the states in implementing contingency plans that include the localized population reduction of the target species in areas where rabies outbreaks occur.

The supplemental EA analyzes a number of environmental issues or concerns with the oral rabies vaccine and with activities associated with ORV programs, such as capturing and handling of animals for monitoring and surveillance purposes and the potential implementation of contingency actions to address rabies outbreaks (i.e., more concentrated localized ORV use or localized suppression of target species populations). The EA also analyzes several alternatives to the proposed action, including no action (i.e., no federal funding or participation by APHIS-WS), live-capture-vaccinate-release programs (i.e., trapping animals followed by administration of injectable vaccines and then release), and ORV bait distribution without animal specimen collections or localized lethal removal of target species under state contingency plans (i.e., no capturing or lethal removal of animals by APHIS-WS for monitoring or surveillance purposes or to address localized rabies outbreaks).

No cumulative impacts have been documented thus far, nor are cumulative impacts anticipated, from the distribution of ORV into the environment. The ORV vaccine and bait that are used have been found safe for target and other animal species, have a negligible risk of causing adverse affects to humans, are readily consumed by target animal species, and do not cause bioaccumulation in the environment. A limited number of baits are distributed one time per year, thereby limiting the potential for persons to be exposed to ORV baits or bait distributing equipment. The analysis in the supplemental EA documented that no significant impacts on the quality of the human environment were expected from APHIS-WS continued or expanded involvement in these programs.

Public Involvement

Several EAs have been prepared previously to analyze the environmental effects of APHIS-WS' continued and expanded participation with an ORV program in several eastern states and Texas. Issues related to the proposed action were identified through involvement and planning/scoping meetings with numerous federal (i.e., Centers for

Disease Control and Prevention), state (i.e., health, agriculture, and natural resource departments), and local government agencies, academic institutions, and Canadian provincial government agencies (i.e., Ontario Ministry of Natural Resources). Additional efforts to determine further issues that the public might have with this action were made through a Federal Register Notice (66 FR 13696-13700, March 7, 2001) and by a second Federal Register Notice (66 FR 27489, May 17, 2001) making the EA available to the public for review and comment prior to an agency decision. A letter was sent to potentially affected or interested American Indian Tribes to assure their opportunity to be involved in the EA process. Comments received were reviewed to identify any substantive new issues or alternatives not already identified for analysis. A third Federal Register Notice (66 FR 45835-45836, August 30, 2001) was published announcing the availability of the EA and Decision/ FONSI. In 2002, a Notice of Availability for a subsequent Decision/FONSI was published through a Federal Register Notice (67 FR 44797-44798, July 5, 2002). In 2003, a Notice of Availability for a supplemental EA and Decision/FONSI was published through a Federal Register Notice (68 FR 38669-38670, June 30, 2003). In 2004, a Notice of Availability for an EA and Decision/FONSI was published through a Federal Register Notice (69 FR 7904-7905, February 20, 2004) in cooperation with the USFS to expand ORV program assistance to National Forest System lands, excluding Wilderness Areas, in several eastern states. Also in 2004, a Notice of Availability for another supplemental EA and Decision/FONSI was published through a Federal Register Notice (69 FR 56992-56993, September 23, 2004) to document the expansion of the rabies management program to include 26 states and the District of Columbia. In response to the expanded program area, another Notice of Availability for a supplemental EA and Decision/FONSI was published through a Federal Register Notice (70 FR 72977-72978, December 8, 2005) in 2005 to document additional National Forest System lands within the expanding program.

Primary Need for Action

If new rabies strains such as those transmitted by raccoons, gray foxes, and coyotes are not prevented from spreading to new areas of the U.S., the health threats and costs associated with rabies are expected to increase substantially as broader geographic areas of the U.S. are affected.

Major Issues

Based on the previous ORV EAs and considerable experience by cooperating agencies and APHIS-WS in addressing concerns expressed by the public in past ORV programs, the following issues were identified for consideration in detail in the EA:

- Potential for adverse effects on people that become exposed to the vaccine or the baits.
- Potential for adverse effects on target wildlife species populations.
- Potential for adverse effects on nontarget wildlife species, including threatened or endangered species.
- Potential for adverse effects on pet dogs or other domestic animals that might consume the baits.
- Potential for the recombined V-RG virus to "revert to virulence" and result in a virus that could cause disease in humans or animals.
- Potential for the V-RG virus to recombine with other viruses in the wild to form new viruses that could cause disease in humans or animals.
- Potential for aerially dropped baits to strike and injure people or domestic animals.
- Cost of the program in comparison to perceived benefits.
- Humaneness of methods used to collect wild animal specimens critical for timely program evaluation or to reduce local populations of target species under state contingency plans.

In addition to the identified major issues considered in detail, ten other issues were considered but not in detail with rationale and further analysis.

Alternatives Analyzed in Detail

Four potential alternatives were developed to address the issues identified in the 2004 supplemental EA. A brief description of each alternative is provided below.

Alternative 1. Proposed Action. (Preferred Alternative). This alternative would involve the continued or expanded

use of federal funds by APHIS-WS to purchase V-RG oral vaccine baits and to participate in their distribution under the authorities of the appropriate state agencies in selected areas of the several states listed in the EA - Section 1.2 to stop or prevent raccoon, gray fox, and coyote rabies, and to assist with monitoring and surveillance efforts by capturing and releasing or killing target species for purposes of obtaining biological samples. APHIS-WS assistance could also include participation in implementing state contingency plans that involve target species population reduction or concentrated ORV baiting in localized areas if rabies outbreaks occur beyond the designated ORV vaccination barriers to stop such outbreaks from spreading.

Alternative 2. No Action. This alternative would imply no involvement by APHIS-WS in rabies prevention or control in the states identified in the EA - Section 1.2. The "No Action" alternative is a procedural NEPA requirement (40 CFR 1502), is a viable and reasonable alternative that could be selected, and serves as a basis for comparison with the other alternatives. The states could still conduct ORV programs without APHIS-WS assistance.

Alternative 3. Live-Capture-Vaccinate-Release Programs. This alternative would involve the live capture of species being targeted (e.g., raccoon, gray fox, coyotes) followed by administration of rabies vaccines by injection and release back into the wild.

Alternative 4. Provide Funds to Purchase and Distribute ORV baits without Animal Specimen Collections or Lethal Removal of Animals under Contingency Plans. Under this alternative, APHIS-WS would provide resources for and assistance in ORV bait distribution only and would not engage in or provide funds for the collection of wild animal specimens for monitoring and project evaluation purposes or for implementation of localized lethal removal actions under state contingency plans. The states could still conduct these activities without APHIS-WS assistance.

Alternatives Considered, but Not Analyzed in Detail

Three alternatives were considered, but not in detail, and are described as follows with rationale:

Depopulation of target species. This alternative would result in the lethal removal of raccoons (in the eastern states listed) and gray foxes and coyotes (in Texas) throughout the zones where outbreaks of the targeted strains of rabies are occurring or are expected to occur. The goal would be to achieve elimination of the rabies strains by severely suppressing populations of the target animal species over broad areas so that the specific strains of rabies could not be transmitted to susceptible members of the same species. This could theoretically stop the forward advance of the disease and potentially result in elimination of the particular rabies variants as infected animals die from rabies before they could transmit it to other members of the same species. This alternative was not considered in detail because of the cost and effort that would be involved and because it would also undoubtedly be opposed by most members of the public.

Population control through birth control. Under this alternative, APHIS-WS would provide funds or operational assistance to implement one or more methods to control populations of the target species by reducing reproduction. Such methods could involve live capture and surgical sterilization, the use of chemical reproductive inhibitors placed out in baits or delivery devices, or the application of *immunocontraception* strategies (i.e., vaccines that can cause infertility in treated animals). This alternative was not considered in detail because of the extreme expense and difficulty involved, the greater effectiveness of vaccination alternatives, and because no contraceptive agents are currently registered for use.

Employ other types of ORV instead of the V-RG vaccine. Under this alternative, APHIS-WS would provide funds to purchase and use "modified-live-virus" (i.e., "attenuated" or weakened strains that have been shown to have little chance of causing rabies in treated animals) or perhaps "killed-virus" (i.e., "inactivated" virus) oral vaccines instead of the V-RG vaccine in ORV baits. This alternative was not considered in detail because some of the vaccines involved have the potential to cause rabies (e.g., "live" virus vaccines), others would be cost-prohibitive to produce in ORV form (e.g., "killed" virus vaccines), and none are currently licensed or approved for any such use in the U.S.

Monitoring

The APHIS-WS rabies management program annually reviews its ORV program impacts on target (raccoons, gray

foxes, and coyotes) and nontarget species to ensure that APHIS-WS activities do not adversely affect the viability of wildlife populations. The EA is also reviewed annually to confirm that the ORV program continues to have negligible impacts on humans, pets, other domestic animals, and the environment and to ascertain whether analysis and data provided in the EA are sufficient.

Program Update – based on the 9 issues that were identified in the EA

1. Potential for adverse effects on people that become exposed to the vaccine or the baits.

Out of 66.3 million baits disbursed since APHIS-WS program inception, only 965 people reported contact with a bait. This equates to 1 human exposure per 68,746 baits distributed (USDA 2007a). In addition, exposure cases are generally insignificant as most involved finding an intact bait or just seeing a bait and reporting it. Very few cases involved touching a broken bait, sachet, or liquid vaccine. Furthermore, of the very few contact cases reported since APHIS-WS ORV program inception in 1995, only 1 known adverse reaction has occurred (USDA 2007a). The case occurred in Ohio in September, 2000, when a woman was bitten by her dog while she tried to remove the bait from her dog's mouth (USDA 2004a, 2007a). The vaccine liquid was exposed to the bite area, resulting in localized inflammation and pox virus lesions at the site of the bite as well as a whole body rash. Most recent reports attribute her response to the vaccinia virus as due likely to the reduced state of immunity typical during pregnancy and due to an underlying skin disorder (epidermolytic hyperkeratosis) that the woman already had. The medical outcome for the woman and her newborn child was favorable and without uncommon incident. A lawsuit was filed in 2001 and a judgment was determined in favor of the defendant, the Ohio Department of Health, in May 2003.

Based on the aforementioned information, risks to humans from contact with the V-RG vaccine are believed to be minimal. The risk and potential severity of adverse effects from rabies exposures in humans would probably be greater without ORV programs than would be the risk of serious adverse effects from vaccinia virus infections with ORV programs. For instance, implementation of ORV programs likely reduces the risk of humans contracting rabies by reducing the chance of encountering rabid animals. Some potential exists for adverse reactions to develop in humans exposed to ORV baits. However, the potential for humans to become exposed to a bait is remote.

2. Potential for adverse effects on target wildlife species populations

Current/historical ORV program areas have demonstrated the safety and effectiveness of the V-RG vaccine in target populations. ORV baits containing the V-RG vaccine have had no adverse impact on target populations. ORV is currently licensed by the USDA for raccoons and coyotes and is approved for experimental use in gray foxes.

Raccoon Update

Raccoon populations can generally be expected to withstand harvest rates of about 49% or more annually (Sanderson 1987, USDA 1997a). The EA (USDA 2004a) states that APHIS-WS and cooperating state or local agencies expect to lethally remove less than 1% of the lowest estimated number of raccoons in all states combined. Removal would primarily only occur during implementation of contingency actions that often integrate enhanced rabies surveillance and ORV, and may include the need for localized population reduction. Target species may also be removed for rabies diagnostic testing during monitoring and surveillance activities if the animal is showing signs of rabies, is sick, or has sustained an injury (e.g., had been hit by a car). There would be no anticipated significant cumulative impacts (i.e., monitoring/surveillance, localized population reduction, annual trapper and hunter harvest, and other mortality) to raccoon populations even if contingency actions are infrequently conducted in small areas of the states involved in ORV programs. Target animals are primarily live-trapped and released during regular monitoring, surveillance, density studies, or other evaluation activities (USDA 2007a).

Raccoons are common throughout the U.S. Population studies indicate that raccoon densities range from less than 1 to 5 individuals/km^2 on the prairies of North Dakota and Manitoba (Fritzell 1978, Cowan 1973) to much higher densities for marshland, bottomlands in the Midwestern and eastern U.S. (Yeager and Rennels 1943, Butterfield 1944, Dorney 1954, Urban 1970, Van Druff 1971). Orloff (1980) recorded a density of 0.9 raccoons/km^2 in rural parts of Contra Costa and Alameda Counties, California. Studies in suburban Cincinnati, Ohio illustrate that residential areas support very high densities of raccoons, as high as 69 individuals/km^2 (Johnson 1970, Hoffman and Gottschang 1977). Riley et al. (1998) report the range of raccoon densities from studies in various habitats as less than 1 in some rural

areas to as high as 333 raccoons/km^2 in an urban national park in Washington, D.C.

Relative densities, along with age structure and sex ratios, serve as indices to raccoon population status and assist in the evaluation of ORV efforts to contain the spread of rabies in raccoons. APHIS-WS has conducted more than 100 raccoon relative density studies since 1997 (USDA 2007a). These studies indicate that density indices, ranging from 0-38 raccoons/km^2 (average of 8 raccoons/km^2), are well within the documented range of estimates reported in other studies. The national rabies management program has expanded and now covers 25 states in the eastern U.S. and, thus, includes many different habitats which support varying raccoon densities. Such habitats include agriculture, forested, urban/suburban, rural, and wetlands. Based on a review of these studies, the rabies management program now defines "low" density habitats as those supporting 0-2 raccoons/km^2, "standard" density as 3-15 raccoons/km^2, and "high" density as ≥16 raccoons/km^2 (USDA 2007a). To date, 13 studies have been placed in the "low" density range, 75 studies occurred within the "standard" density range, and 7 studies were within the "high" density range. Several of the 13 studies in the "low" density range specifically targeted areas suspected of supporting relatively low raccoon densities (e.g., contiguous northern hardwood, spruce-fir, or coastal pine-oak habitats) (USDA 2007a).

Currently, 15 states, out of the 25 eastern states covered under the national rabies management program and supplemental EA, participate in ORV-related activities. Raccoon density estimates are considerably lower than the density studies and literature indicate for the majority of habitats that occur within the states in this program (USDA 2007a). Conservative population density estimates are used to ensure lethal removal of less than 1% of the population. For program purposes, the rabies management program determined the lowest estimated mean density to range from 1.5 and 8 raccoons/km^2. Thus, the lowest estimated size of the raccoon population totaled from the 15 eastern states is between 2,004,348 and 10,689,856 raccoons (USDA 2007a). Since preparation of the first ORV-related EA in 2001 and data analyzed for program activities through 2005 (USDA 2007a, 2005, 2004c, 2004d, 2003b), a total of 3,749 raccoons have been euthanized (ranging from 595 – 1,104 raccoons euthanized annually in the five years of analysis thus far). In contrast, a total of 17,002 raccoons have been captured and released between 2001 and 2005 (ranging from 1,352 – 5,421 raccoons released annually). Based on these numbers, lethal removal has accounted for less than 0.01% to 0.06% of the total lowest estimated population annually (USDA 2007a, 2005, 2004c, 2004d, 2003b). Therefore, the rabies management program continues to have no adverse impacts to raccoon densities. In the absence of the ORV program, it is highly likely that substantially greater numbers of raccoons would succumb to the invariably fatal rabies virus than are removed during contingency actions or surveillance and monitoring activities. These activities are integral to preserving the integrity of the ORV program, preventing rabies spread among raccoons to areas not infected with this fatal virus, and for monitoring program effectiveness.

Coyote and Gray Fox Update

The ORV program in Texas targets coyote and gray fox strains of the rabies virus. Coyote and gray fox populations can generally be expected to withstand annual harvest rates of about 70% and 25% or more, respectively (USDA 2006b). Between 2001 and 2005, cumulative take (private harvest rates combined with APHIS-WS management actions including the ORV program) in Texas averaged approximately 8% of the population for coyotes and less than 2% for gray foxes, far below the sustainable harvest level (USDA 2007a, 2005, 2004c, 2004d, 2003b). The number of coyotes and gray foxes removed annually by the APHIS-WS ORV program alone equates to approximately 0.19% (average of 106 coyotes) and 0.05% (average of 104 gray foxes), respectively, of their estimated populations (USDA 2007a, 2005, 2004c, 2004d, 2003b). Therefore, cumulative impacts (i.e., monitoring and surveillance, localized population reduction, annual trapper and hunter harvest, and other mortality) to both coyote and gray fox populations are negligible. The ORV program continues to have no adverse impacts to coyote or gray fox densities. Furthermore, in the absence of the ORV program, it is highly likely that far more coyotes and gray foxes would die from rabies than are killed for surveillance and monitoring purposes.

The rabies management program's lethal removal of far less than 1% of target species did not reduce statewide or regional densities of target species. As a result of review of potential impacts to target species, the potential for adverse, cumulative impacts continues to be negligible.

3. Potential for adverse effects on nontarget wildlife species, including threatened or endangered species.

More than 50 wildlife species from Europe and North America have been tested, including relevant taxonomic groups

believed to be potentially at risk for contact with the RABORAL V-RG® vaccine. Rupprecht et al. (1992) reported V-RG is safe in all species (more than 350 individual animals) tested to date (USDA 2004a). Thus, nontarget species would not be expected to experience any effect other than possibly becoming immunized against rabies.

The EA (USDA 2004a) states that ORV programs and methods used in capture/removal of target species in monitoring activities or contingency plan implementation would have no effect on any listed threatened or endangered (T&E) species. The methods used in rabies monitoring and surveillance or in implementing localized population reduction under state contingency actions would have no significant adverse effects on nontarget species. Nontargets would be released unharmed if incidentally caught in cage traps and shooting is essentially 100 percent selective for target species.

Annual reporting since preparation of the first ORV-related EA in 2001 and data analyzed for program activities through 2005 (USDA 2007a, 2005, 2004c, 2004d, 2003b) indicate that nontarget populations have not been adversely affected by APHIS-WS actions. No reports have been received regarding nontarget wildlife experiencing adverse reactions to baits. Nontarget wildlife species have been incidentally captured during ORV monitoring and surveillance efforts. A total of 8,210 nontargets were captured between 2001 and 2005 (USDA 2007a, 2005, 2004c, 2004d, 2003b). Most species were captured in cage traps and released unharmed (7,151 nontargets were released out of the total capture of 8,210). Some nontarget animals were euthanized (1,059 nontargets were euthanized out of the total capture of 8,210 between 2001 and 2005) for rabies diagnostic testing, if they were injured, or if they were demonstrating strange behavior symptomatic of the rabies virus (USDA 2007a, 2005, 2004c, 2004d, 2003b). The nontargets that were euthanized were not considered to be from low density populations and removal was not expected to have any cumulative adverse effects on populations in the area.

No T&E species were adversely affected by APHIS-WS' actions between 2001 and 2005. During this time, a total of three T&E species were incidentally captured and all three were released unharmed. The species included two American alligators in Florida and 1 river otter in Ohio (USDA 2007a, 2005, 2004c, 2004d, 2003b). The American alligator was delisted in 1987 and reclassified as "threatened due to similarity of appearance (T-S/A)" [50 CFR 17.42(a)] to the endangered crocodile. This federal designation regulates commercial sale and trade of alligator skins and other products. Because the animal was released unharmed, APHIS-WS did not violate the spirit of the "similarity of appearance" designation of the Endangered Species Act. River otters were previously state-listed in Ohio, but have since been delisted due to rapidly increasing numbers of the species throughout Ohio. Yearly reviews of T&E species listed by each state and the U.S. Fish and Wildlife Service indicate that no species, besides those currently analyzed in the EA (USDA 2004a), have been added to T&E lists that may be adversely affected by the ORV program. Therefore, APHIS-WS' determination of no effect is still valid for the proposed action. APHIS-WS concludes that the cumulative impact on nontarget species is negligible to nonexistent and that APHIS-WS has not adversely affected the viability of any wildlife species populations.

4. Potential for adverse effects on pet dogs or other domestic animals that might consume the baits.

Rupprecht et al. (1992) and Pastoret et al. (1995) summarized the results of RABORAL V-RG® safety trials in nontarget species (USDA 2004a). The studies included oral vaccination of domestic dogs, cats, cattle, and sheep and found no adverse effects on those species. In addition, more than 66.3 million ORV baits using the V-RG vaccine have been distributed in the U.S. between 1995 and 2005 with no reported adverse effects on domestic animals. Between 1995 and 2005, 724 instances have been reported where a pet or other domestic animal had contact with a bait (i.e., carrying bait in mouth, chewing bait, vomiting sachet, etc. are considered "contact" or "exposures" for the purposes of this document). This equates to 0.001% contact cases or 1 domestic exposure per 91,630 baits disbursed (USDA 2007a). APHIS-WS concludes that adverse cumulative impacts to pets and other domestic animals continue to be negligible.

5. Potential for the recombined V-RG virus to "revert to virulence" and result in a virus that could cause disease in humans or animals.

Studies show that the V-RG recombinant virus is genetically stable and would not become virulent (capable of causing disease) after it replicates in animals that eat ORV baits containing the RABORAL V-RG® vaccine and, therefore, would not be transmitted to other animals [addressed in the EA (USDA 2004a) and formal Risk

Assessments by USDA-APHIS].
The EA (USDA 2004a) concluded that effects of this issue would be negligible. Potential impacts of this issue have not changed from those analyzed in the EA. Impacts of the program on this issue are expected to remain insignificant or nonexistent (USDA 2007a).

6. Potential for the V-RG virus to recombine with other viruses in the wild to form new viruses that could cause disease in humans or animals.

Studies have shown that adverse environmental effects from spontaneous recombination of V-RG with other wild viruses are exceedingly unlikely. This is further supported by the fact that there have been no observed adverse effects in wildlife and humans both in Europe and North America following a number of years of experimental and field use of the RABORAL V-RG® vaccine (USDA 2004a).

The EA (USDA 2004a) concluded that effects of this issue would be negligible. Potential impacts of this issue have not changed from those analyzed in the EAs. Impacts of the program on this issue are expected to remain insignificant or nonexistent (USDA 2007a).

7. Potential for aerially dropped baits to strike and injure people or domestic animals.

ORV baits are distributed from aircraft at an average density of 27/km^2 in the coyote rabies zone and 39/km^2 in the gray fox rabies zone in Texas. Baiting density averages 75/km^2 in eastern states where the raccoon rabies variant is targeted (USDA 2004a). Those densities are sparse enough to predict that the chance of a person being struck and harmed by a falling bait is extremely remote.

More than 66.3 million baits have been distributed in the U.S. by APHIS-WS between 1995 - 2005 and only 10 incidents have been reported in which a person claimed to have been struck by a falling bait (0.00001% chance of being struck by a bait or 1 strike per 6.6 million baits dropped) (USDA 2007a). None of the reports since APHIS-WS' ORV program inception have resulted in any injury or harm to the individuals involved (USDA 2007a). In addition, trained air crews avoid dropping baits into cities, towns, and other areas with human dwellings, or if humans are observed below. In areas of higher human density, ground placement of baits is normally used. Thus, the potential of falling baits striking people, domestic animals, or property continues to be insignificant. Impacts of the program on this issue are expected to remain negligible.

8. Cost of the program in comparison to perceived benefits.

New information continues to be published regarding the costs and benefits of managing rabies. A recent article (Sterner and Sun 2004) discusses new cost-benefit data and will be cited in future rabies management-related EAs. Since this information was not available for the 2004 EA, it seemed pertinent to provide a brief synopsis of the article here. Sterner and Sun (2004) describe a comprehensive model of the costs attributed to rabies. They analyzed minimum-maximum estimates of the individual event costs (i.e., per unit cost) for 11 factors in attempt to reduce the uncertainty of economic costs linked with rabies and to identify key sources of potential savings as a result of rabies management activities. The 11 factors included: 1) pet vaccination, 2) livestock vaccination, 3) pet replacement, 4) livestock replacement, 5) pre-exposure prophylaxis, 6) post-exposure prophylaxis, 7) adverse reactions, 8) public health, 9) animal control, 10) quarantine, and 11) human death. Sterner and Sun (2004) stated that although pet vaccination and post-exposure prophylaxis have traditionally been cited as the major cost impacts of the disease, they found that the maximum and largest ranges of per unit costs were associated with livestock replacement, post-exposure prophylaxis, animal replacement, and human death. These factors help reduce the uncertainty surrounding the economic impacts of wildlife rabies and the management of this deadly virus for making informed policy decisions.

APHIS-WS continues to research methods that will reduce costs in managing rabies. Surveillance activities were conducted to assess aerial and/or ground ORV baiting efficacy, summer versus fall baiting schedules, and seasonal raccoon movement in a number of states. Numerous density studies were also conducted in the majority of participating states to determine raccoon densities in relation to habitat, elevation, and numbers of baits distributed. In areas where raccoon densities are low, the number of baits distributed may be reduced to increase cost effectiveness of

the ORV program. The rabies management program continues to utilize natural barriers, such as mountains and rivers, in the configuration of baiting zones to reduce the number of baits used. In addition, ORV baiting strategies, such as the appropriate distance between flight lines to maximize bait uptake by target species, is assessed annually. Furthermore, studies are on-going in attempt to identify the most effective bait formulation and palatability for the target species (USDA 2007a, 2007b).

9. Humaneness of methods used to collect wild animal specimens critical for timely program evaluation or to reduce local populations of target species under state contingency plans.

APHIS-WS has policies in place that give direction toward the achievement of the most humane program possible while still accomplishing the program's mission. APHIS-WS has made modifications to management devices through research and development which have increased selectivity toward the species being targeted. Research is continuing with the goal of bringing new findings and products into practical use. In addition, ORV program methods may induce less suffering than if the animal contracted rabies.

ORV Program and Contingency Actions

Proposed Action – Alternative 5

The proposed action for this Decision document involves a combination of Alternative 1 (Proposed Action) and Alternative 3 (Live-Capture-Vaccinate-Release Only) from the 2004 supplemental EA. The former proposed action included the use of several contingency actions as part of the ORV program; however it did not address trap-vaccinate-release as one of them. This new proposed action better defines and identifies the types of contingency actions that may be used as part of the ORV program. The combination of Alternatives 1 and 3 from the 2004 supplemental EA will be termed Alternative 5 for the purposes of this Decision document. Combined, the two alternatives capture the essence of the expanding and developing ORV program.

Defining the Term "Contingency Actions"

Rabies emergencies requiring contingency actions may be categorized as: Type 1) index rabies case(s) that occur well beyond (e.g., raccoon rabies is detected greater than 80 km [50 miles] west of its known current distribution) ORV barriers (likely due to translocation of a rabid animal); Type 2) rabies case(s) that occur just beyond established ORV zones; Type 3) rabies case(s) that occur where no ORV zone has been created; Type 4) persistence of rabies cases within ORV zones created as emergency treatments (e.g., northeast Ohio); Type 5) rabies hotspots found within the ORV zones that represent a high risk of spreading; and Type 6) aggressive epizootics (large numbers of infected animals in a relatively small area) approaching an established ORV zone that potentially could spread through the treatment area.

To address these 6 types of emergencies, contingency actions may be used to: delineate the scope and intensity of outbreaks, contain outbreaks, restore the integrity of ORV zones, and prevent further spread of the rabies virus. Contingency actions may include a single action or the integration of two or more of the following:
1) Enhanced surveillance, which may include capture and release or euthanasia of target and specific nontarget animals for rabies testing.
2) Treatment with increased bait density (e.g., 75 baits/km^2 is considered the standard bait density for raccoons) to ensure sufficient baits for high density of target species or to bolster antibody response under "normal" target species densities.
3) Increase baiting frequency more than once/year.
4) Trap-Vaccinate-Release (TVR) of targets and specific nontargets, such as skunks and feral cats that are known to harbor and transmit rabies. A licensed parenteral (injectable) vaccine, such as IMRAB® 3 (MERIAL LTD), rather than the oral rabies vaccine, would be used during the TVR contingency action. This action would involve the live capture of species being targeted (e.g., raccoons) followed by administration of rabies vaccines by injection and release back into the wild. Currently, no vaccine is specifically licensed for this type of use (CDC 2000). However, certain injectable vaccines may be used "off-label" under the direction of veterinarians to vaccinate wild animal species in

certain situations (J. Mitzel, APHIS-Veterinary Services, pers. comm. 2001). Injectable vaccines, such as IMRAB® 3, are killed virus rabies vaccines recommended for the vaccination of healthy pets and other domestic animals (e.g., cats, dogs, horses, sheep, cattle, and ferrets). They contain the same virus strain that is used in the Pasteur Merieux Connaught human vaccine. TVR has been used successfully in various locals in Canada (i.e., New Brunswick, St. Lawrence River region, Ontario, etc.) as part of an integrated rabies management program to eliminate or stop the spread of specific variants of the rabies virus in raccoons and skunks (Rosatte et al. 1990, 1992, 2001).
5) Localized target species population reduction.
The least intrusive contingency actions involve increasing levels of surveillance to determine if additional action is warranted.

Some examples of contingency actions currently occurring within the rabies management program include:
An area near Knoxville, Tennessee is currently experiencing a Type 3 emergency situation. The case is located between the Appalachian Ridge and Georgia-Alabama-Tennessee (GAT) ORV barriers and requires, at minimum, enhanced rabies surveillance to determine if other cases may be present as a result of an index case of raccoon variant of rabies in a red fox. This case occurred just west of high elevation habitat which is generally not known to facilitate rabies spread due to low raccoon population densities. Thus, no barrier was in place when this case occurred. Subsequent surveillance has not resulted in detection of additional cases and at this time no additional action has been taken.

Recent research findings of infrequent long range gray fox movement from within an existing ORV zone, designed to contain and eliminate gray fox rabies in west central Texas, underscores the need to reinforce the existing ORV zone - a Type 5 emergency. Emergency resources have been applied to widen the ORV zone in critical locations to prevent movement of the virus beyond the barrier by a single rabid fox.

During 2004, Ohio identified its first case of raccoon variant of the rabies virus in Lake County, located 10.6 km west of the existing ORV zone. Additional raccoon rabies cases were detected in the area from enhanced and public health surveillance (45 rabid raccoons and one skunk positive for raccoon rabies were confirmed within Geauga, Lake, and Cuyahoga Counties) in Ohio. This emergency (Types 2 and 4) triggered a contingency action response, which encompassed a 2,471 km^2 area in 2004. The initial response was enhanced rabies surveillance and TVR, followed by the distribution of 98,565 ORV baits. Through calendar year 2006, seven cases persisted within the contingency action treatment area. In the spring of FY 2007, TVR is planned and will be complemented by ORV in spring and fall.

In 2004, New York initiated cooperative enhanced rabies surveillance and control on Long Island (Nassau County) in response to a rabies outbreak (Type 3 emergency). This is the first time raccoon rabies has been documented on Long Island. Enhanced surveillance was implemented to better document the location and scope of the outbreak prior to vaccination efforts in raccoons to prevent further spread of rabies. As a result of enhanced surveillance efforts within a 2-mile radius of the index case, 10 raccoons were confirmed with raccoon rabies in Nassau County. TVR was implemented (more than 400 raccoons were vaccinated with injectable rabies vaccine) and ORV baits were distributed in a 171 km^2 zone around the positive cases. The contingency effort on Long Island focused on creating a rabies-immune raccoon population in the target zone to prevent additional cases. High densities of raccoons on Long Island increase the likelihood for humans, pets, or other domestic animals to encounter a rabid raccoon; thus the spread of raccoon rabies is of great concern.

Contingency action planning and implementation is an integral component of rabies control with ORV as emergencies may be expected and may be predicted as ORV zones are created over broader landscape to contain raccoons or other variants of the rabies virus in carnivores. High risk rabies emergencies must be treated in a timely fashion so they can be contained to preserve the integrity of ORV zones created to serve as barriers to rabies spread. Enhanced surveillance is critical to delineate the distribution and intensity of outbreaks prior to or concomitantly with control such s TVR, ORV or localized population reduction, as well as to measure program success.

Environmental Consequences of Alternative 5 (ORV Program Plus Five Contingency Actions)

APHIS-WS has determined that the information and environmental analysis provided in the EA (USDA 2004a), combined with the additional information and analysis contained in this Decision, is valid and appropriate for

determining the potential environmental impacts of utilizing contingency actions in the event of rabies emergencies. Therefore, APHIS-WS has determined that the EA and additional information and analysis in this Decision are adequate to make an informed decision of APHIS-WS potential environmental impacts from the use of contingency actions. The following are the anticipated environmental impacts from the five types of contingency actions that may be used during rabies emergencies.

1. Potential for adverse effects on people that become exposed to the vaccine or the baits.

The EA concluded that the ORV program has a negligible adverse risk or effect to humans from exposure to the vaccine or baits. A similar impact is expected with regard to Contingency Action 2 (treatment with increased bait density to ensure sufficient baits for high density of target species or to bolster antibody response under "normal" target species densities) and Contingency Action 3 (increase baiting frequency more than once/year). The potential for humans to become exposed to a bait is remote (1 human contact per 68,746 baits distributed under current baiting practices – USDA 2007a), even with an increase in baiting density or frequency during localized contingency actions.

Oral rabies vaccines and baits are not used during Contingency Action 1 (enhanced surveillance, which may include capture and release or euthanasia of target and specific nontarget animals for rabies testing) or Contingency Action 5 (localized target species population reduction). Thus, there would be no effect on people with regard to vaccine exposure.

Contingency Action 4 (TVR of targets and specific nontargets) involves the use of a parenteral (injectable) vaccine on the specific animal that is trapped. Therefore, the general public would not be exposed to this type of vaccine. Biologists and/or veterinarians using the vaccine would follow the proper handling procedures during TVR activities. Thus, injectable vaccines would have no adverse effect on people.

2. Potential for adverse effects on target wildlife species populations.

The EA concluded that the ORV program has a negligible adverse risk or impact to target wildlife species. A similar impact is expected with regard to the 5 types of contingency actions defined previously.

Contingency Action 2 (treatment with increased bait density to ensure sufficient baits for high density of target species or to bolster antibody response under "normal" target species densities) and Contingency Action 3 (increase baiting frequency more than once/year) utilize ORV. Current/historical ORV programs and research conducted on the V-RG vaccine have demonstrated its safety and effectiveness in target populations. The V-RG vaccine is currently licensed by the USDA for raccoons and coyotes and is approved for experimental use in gray foxes.

Contingency Action 1 (enhanced surveillance, which may include capture and release or euthanasia of target and specific nontarget animals for rabies testing) and Contingency Action 5 (localized target species population reduction) involve the possible removal of target species. As discussed previously in the Program Update section, raccoon, coyote, and gray fox populations can generally be expected to withstand harvest rates of about 49%, 70%, and 25% or more annually (Sanderson 1987, USDA 1997a, USDA 2006b), respectively. The EA states that APHIS-WS and cooperating state or local agencies expect to lethally remove less than 1% of the lowest estimated number of raccoons in all states combined. To date, lethal removal has accounted for less than 0.01% to 0.06% of the total lowest estimated raccoon population annually (USDA 2007a, 2005, 2004c, 2004d, 2003b). The ORV program in Texas targets coyote and gray fox variants of the rabies virus. The number of coyotes and gray foxes removed annually by the APHIS-WS ORV program equates to approximately 0.19% and 0.05%, respectively, of their estimated populations (USDA 2007a, 2005, 2004c, 2004d, 2003b). The APHIS-WS rabies management program's lethal removal of far less than 1% of target species did not reduce statewide or regional densities of target species. As a result of review of possible impacts to target species, the potential for adverse cumulative impacts continues to be negligible. Therefore, the rabies management program continues to have no adverse impacts to target species densities. In the absence of the ORV program, it is highly likely that substantially greater numbers of raccoons would succumb to the invariably fatal rabies virus than are removed during contingency actions or other rabies management activities. These activities are integral to preserving the integrity of the ORV program, preventing rabies spread among raccoons, coyotes, and gray foxes to areas not infected with this fatal virus, and for monitoring program effectiveness.

Contingency Action 4 (TVR) involves the use of a parenteral (injectable) vaccine, such as IMRAB® 3, which can be used "off label" under the direction of veterinarians to vaccinate healthy wildlife. After being vaccinated against the rabies virus, healthy target species would be released at the site of capture. Therefore, injectable vaccine use would have no adverse effects on target species. Beneficial impacts include bolstering target species population immunity and preventing further rabies spread. Sick or injured target animals would likely be euthanized for rabies testing. Impacts of euthanasia and lethal removal on target species populations were discussed in this section under Contingency Action 1.

3. Potential for adverse effects on nontarget wildlife species, including threatened or endangered species.

The EA concluded that the ORV program has a negligible adverse risk or effect on nontarget wildlife and would have no effect on any T&E species. A similar impact is expected with regard to the 5 types of contingency actions defined previously.

Contingency Action 2 (treatment with increased bait density to ensure sufficient baits for high density of target species or to bolster antibody response under "normal" target species densities) and Contingency Action 3 (increase baiting frequency more than once/year) utilize ORV. As discussed previously in the Program Update section and analyzed in the EA, more than 50 wildlife species from Europe and North America have been tested, including relevant taxonomic groups believed to be potentially at risk for contact with the RABORAL V-RG® vaccine. Rupprecht et al. (1992) reported that the V-RG vaccine is safe in all species (more than 350 individual animals) tested to date. In addition, there is no evidence of potential harm to target or nontarget species from overdosage of V-RG vaccine by any route or from multiple doses (Rupprecht et al. 1992). Few nontarget species are likely attracted to the ORV baits, and the few carnivore species that might consume baits would be expected to experience no effect other than possibly becoming immunized against rabies. The ORV program may instead reduce the likelihood of rabies virus exposure by wildlife, including protected species.

Contingency Action 1 involves enhanced surveillance, which may include capture and release or euthanasia of specific nontarget animals for rabies testing. Nontarget wildlife species have been incidentally captured during ORV monitoring and surveillance efforts. As discussed previously in the Program Update section and in the EA, over 5 years of data for the ORV program indicate that 87% of nontargets (7,151 nontargets were released out of the total capture of 8,210) were released at the site of capture. The remaining (13%) nontargets were euthanized for rabies diagnostic testing, if they were sick, injured, or were demonstrating strange behavior symptomatic of the rabies virus. The nontargets that were euthanized were not considered to be from low density populations and removal was not expected to have any cumulative adverse effects on populations in the area. Any T&E species incidentally trapped during surveillance activities were released unharmed. Therefore, nontarget populations would not be adversely affected by trapping methods used during enhanced surveillance.

Contingency Action 5 (localized target species population reduction). Some of the methods proposed for use in collecting target species within ORV zones or other contingency action locations have the potential for accidentally catching or killing nontarget animals (i.e., cage traps, leghold traps, or snares). However, measures such as size or location of traps and types of baits used help to minimize the potential for capturing nontargets. Methods such as ground-based and aerial shooting have no effect on nontarget species as they are essentially 100 percent selective for target species. APHIS-WS has analyzed the effects on nontarget species by such methods in numerous EAs, including this EA, which found no significant adverse effects on populations (USDA 2004a, USDA 1997b-j).

Contingency Action 4 (TVR of targets and specific nontargets, such as skunks and feral cats that are known to harbor and transmit rabies) involves the use of a parenteral (injectable) vaccine, such as IMRAB® 3, which can be used "off label" under the direction of veterinarians to vaccinate healthy wildlife. Although targeted species include raccoons in the eastern U.S. and coyotes and gray foxes in Texas, some nontargets have a propensity for contracting, harboring, and spreading the rabies virus which complicates rabies control. Therefore, some nontarget wildlife species, such as skunks, may be vaccinated if incidentally captured during TVR activities. Healthy nontarget animals that are vaccinated should exhibit no effect other than becoming immunized against rabies. The majority of nontargets would be released at the site of capture, whether vaccinated or not. As described above in Contingency Action 1, nontargets would be euthanized for rabies diagnostic testing, if they appear sick, injured, or are demonstrating strange behavior symptomatic of the rabies virus.

4. Potential for adverse effects on pet dogs or other domestic animals that might consume the baits.

The EA concluded that the ORV program had a negligible risk of adversely affecting pet dogs or other domestic animals that might consume ORV treated baits. A similar impact is expected with regard to Contingency Action 2 (treatment with increased bait density to ensure sufficient baits for high density of target species or to bolster antibody response under "normal" target species densities) and Contingency Action 3 (increase baiting frequency more than once/year). Rupprecht et al. (1992) and Pastoret et al. (1995) summarized the results of RABORAL V-RG® safety trials in nontarget species (USDA 2004a). The studies included oral vaccination of domestic dogs, cats, cattle, and sheep and found no adverse effects on those species. In addition, more than 66.3 million ORV baits using the V-RG vaccine have been distributed in the U.S. with no reported adverse effects on pets or other domestic animals. The potential for domestic animals to become exposed to a bait is remote, even with an increase in baiting density or frequency during localized contingency actions. A beneficial effect involved includes the possibility of vaccinating strays and other previously unvaccinated pets, thereby immunizing them against the rabies virus.

Oral rabies vaccines and baits are not used during Contingency Action 1 (enhanced surveillance, which may include capture and release or euthanasia of target and specific nontarget animals for rabies testing) or Contingency Action 5 (localized target species population reduction), therefore, there would be no effect on domestic animals with regard to vaccines or baits. Some of the methods proposed for use in collecting target species within ORV zones or other contingency action locations have the potential for accidentally catching or killing free-roaming, domestic animals (i.e., cage traps, leghold traps, or snares). However, measures such as size or location of traps and types of baits used help to minimize the potential for capturing nontargets, including domestic animals. Methods such as ground-based and aerial shooting have no effect on nontarget species as they are essentially 100 percent selective for target species. APHIS-WS has analyzed the effects on nontarget species by such methods in numerous EAs, including this EA, which found no significant adverse effects on populations (USDA 2004a, USDA 1997b-j). Pets and other domestic animals captured incidentally in traps would either be released at the site of capture or brought to the local animal control shelter.

Contingency Action 4 (TVR of targets and specific nontargets, such as skunks and feral cats that are known to harbor and transmit rabies) involves the use of a parenteral (injectable) vaccine, such as IMRAB® 3, on the specific animal that is trapped rather than the V-RG vaccine and bait. Although targeted species include raccoons in the eastern U.S. and coyotes and gray foxes in Texas, some nontargets have a propensity for contracting, harboring, and spreading the rabies virus which complicates rabies control. Therefore, some nontarget animals, such as feral, collarless cats, may be vaccinated if incidentally captured during TVR activities. Injectable vaccines are registered for use on healthy domestic mammals and, therefore, should exhibit no effect other than becoming immunized against rabies. Sick or injured feral cats would not be vaccinated, but would instead be brought to the local animal control shelter for evaluation and possible rabies testing.

5. Potential for the recombined V-RG virus to "revert to virulence" and result in a virus that could cause disease in humans or animals.

The EA concluded that the ORV program had a negligible risk of causing disease in humans and animals. A similar impact is expected with regard to Contingency Action 2 (treatment with increased bait density to ensure sufficient baits for high density of target species or to bolster antibody response under "normal" target species densities) and Contingency Action 3 (increase baiting frequency more than once/year). The V-RG vaccine is not used in Contingency Action 1 (enhanced surveillance, which may include capture and release or euthanasia of target and specific nontarget animals for rabies testing), Contingency Action 4 (TVR of targets and specific nontargets, such as skunks and feral cats that are known to harbor and transmit rabies), and Contingency Action 5 (localized target species population reduction). Therefore, APHIS-WS has determined no effect regarding this potential issue.

6. Potential for the V-RG virus to recombine with other viruses in the wild to form new viruses that could cause disease in humans or animals.

The EA concluded that the ORV program had a negligible risk of causing disease in humans and animals. A similar impact is expected with regard to Contingency Action 2 (treatment with increased bait density to ensure sufficient

baits for high density of target species or to bolster antibody response under "normal" target species densities) and Contingency Action 3 (increase baiting frequency more than once/year). The V-RG vaccine is not used in Contingency Action 1 (enhanced surveillance, which may include capture and release or euthanasia of target and specific nontarget animals for rabies testing), Contingency Action 4 (TVR of targets and specific nontargets, such as skunks and feral cats that are known to harbor and transmit rabies), and Contingency Action 5 (localized target species population reduction). Therefore, APHIS-WS has determined that adverse effects regarding this potential issue would be minimal.

7. Potential for aerially dropped baits to strike and injure people or domestic animals.

The EA concluded that the ORV program had a negligible risk of injury to people or domestic animals from being struck by aerially dropped baits. A similar impact is expected with regard to Contingency Action 2 (treatment with increased bait density to ensure sufficient baits for high density of target species or to bolster antibody response under "normal" target species densities) and Contingency Action 3 (increase baiting frequency more than once/year). Bait distribution densities are sparse enough to predict that the chance of a person being struck and harmed by a falling bait is extremely remote. In fact, the chance of being struck by a bait is 1 per 6.6 million baits dropped (USDA 2007a). In addition, trained air crews avoid dropping baits into cities, towns, and other areas with human dwellings, or if humans are observed below. In areas of higher human density, ground placement of baits is normally used. Thus, the potential of falling baits striking people, domestic animals, or property continues to be insignificant, even with an increase in baiting density or frequency during localized contingency actions.

ORV baits are not used during Contingency Action 1 (enhanced surveillance, which may include capture and release or euthanasia of target and specific nontarget animals for rabies testing), Contingency Action 4 (TVR of targets and specific nontargets, such as skunks and feral cats that are known to harbor and transmit rabies), and Contingency Action 5 (localized target species population reduction). Therefore, APHIS-WS has determined that adverse effects regarding this potential issue would be minimal.

8. Cost of the program in comparison to perceived benefits.

The EA concluded that the expected benefits of the ORV program will exceed the costs of the program. A similar impact is expected with regard to the 5 types of contingency actions defined previously. Contingency actions, such as TVR and population reduction, may be more labor intensive and time consuming, but these actions are conducted relatively infrequently and on a localized scale to prevent the spread of rabies during emergency situations. When used as part of an integrated rabies management program with ORV, the benefits (i.e., bolstering population immunity, stopping disease spread to new areas) likely outweigh the costs involved.

9. Humaneness of methods used to collect wild animal specimens critical for timely program evaluation or to reduce local populations of target species under state contingency plans.

The EA concluded that capture and handling methods would be viewed by some persons as inhumane, although these methods may induce less suffering than if the animal contracted rabies. A similar impact is expected with regard to the contingency actions defined previously that involve capture methods, handling, euthanasia, and localized population reduction.

Summary

Four potential alternatives were developed to address the issues identified in the 2004 supplemental EA. As the ORV program continues to expand and develop, the need to better define contingency actions to address rabies emergency situations was determined. Thus, this Decision document proposes an additional alternative – Alternative 5 (a combination of Alternatives 1 and 3) – as the new Proposed Action. Table 1 below presents a comparison of the alternatives and anticipated environmental consequences (impacts) of the 5 alternatives. Based upon the analysis provided in the EA and in this Decision document, APHIS-WS has determined that adverse environmental impacts on the quality of the human environment from expanding the ORV program to include 5 contingency actions will be insignificant.

Table 1: Issues/Impacts/Alternatives/Comparison

Issues/Impacts	Alt. 1: 2004 Supplemental EA Proposed Action (provide APHIS-WS funds for ORV and monitoring/ surveillance, potential localized target species population reduction)	Alt. 2: No Action (no APHIS-WS funds for rabies control provided)	Alt. 3: Live Capture/Vaccinate and Release	Alt. 4: Provide Funds for ORV without Lethal Animal Collections or Removals	Alt. 5: 2007 Decision/FONSI Proposed Action (ORV program as described in Alt. 1 with contingency actions that include Alt. 3)
Potential for adverse effects on people that become exposed to the vaccine or the baits.					
• Potential to cause rabies in humans.	No probable risk.	No probable risk from ORV use by states. Higher risk of human rabies cases if states are unable to stop the spread of rabies without federal assistance.	No probable risk.	No probable risk from ORV use; higher risk of human rabies cases if reduced monitoring and surveillance reduces effectiveness of ORV programs.	No probable risk.
• Potential for vaccinia virus to cause disease in humans	Possible but risk is low; risk of significant adverse effects on individuals that experience vaccinia infections also is low.	Slightly lower risk than Alt. 1; states would likely still conduct ORV programs, but probably on a lesser scale without federal assistance.	No risk.	Possible but risk is low; risk of significant adverse effects on individuals that experience vaccinia infections also is low (same as Alt. 1).	Possible but risk is low; risk of significant adverse effects on individuals that experience vaccinia infections also is low.
• Potential to cause cancer (oncogenicity).	No probable risk.	No probable risk.	No probable risk.	No probable risk.	No probable risk.
Potential for adverse effects on target wildlife species populations.					
• Effects of the ORV V-RG vaccine on raccoons, gray foxes, and coyotes	No probable risk of adverse impacts.	No probable risk; states would likely still conduct ORV programs, but probably on a lesser scale without federal assistance.	No risk from V-RG vaccine.	No probable risk of adverse impact (same as Alt 1).	No probable risk of adverse impacts from V-RG vaccine or injectable vaccines used in TVR activities.
• Effects of monitoring and surveillance and localized population reduction actions on raccoon populations in eastern states.	Very low impact.	Slightly lower impact than Alt. 1; states would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Very low impact (similar to Alt. 1).	Slightly lower impact than Alt. 1; states would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Very low impact (similar to Alt. 1 and 3).
• Effects of monitoring and surveillance and localized population reduction actions on gray fox populations in Texas.	Low impact.	Slightly lower impact than Alt. 1; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Low impact (similar to Alt. 1).	Lower impact than Alt. 1; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Low impact (similar to Alt. 1 and 3).

Table 1: Issues/Impacts/Alternatives/Comparison

• Effects of monitoring and surveillance and localized population reduction actions on coyote populations in Texas.	Low impact.	Slightly lower impact than Alt. 1; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Low impact (similar to Alt. 1).	Lower impact than Alt. 1; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Low impact (similar to Alt. 1 and 3).
Potential for adverse effects on nontarget wildlife species, including threatened or endangered species.					
• Effects of the RABORAL V-RG® vaccine on nontarget wildlife including threatened or endangered species.	No effect on T&E species; No probable risk of adverse effects on other nontarget species.	No probable risk of adverse effects from ORV vaccine; but greater risk of adverse effects on these species from rabies.	No effect on T&E species; no risk of adverse effect on other species from ORV vaccine.	No effect on T&E species; No probable risk of adverse effects on other nontarget species (Same as Alt. 1); but greater risk of adverse effects on these species from rabies if reduced monitoring and surveillance reduces effectiveness of ORV programs.	No effect on T&E species; No probable risk of adverse effects on other nontarget species.
• Effects of capture/removal methods (used in monitoring, surveillance, and localized population reduction) on nontarget species, including threatened or endangered species.	No effect on T&E species; Very low risk of adverse effects on other nontarget species.	Probably slightly less impact than Alt. 1.	Less impact than Alt. 1.	Less impact than Alt. 1; states would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	No effect on T&E species; Very low risk of adverse effects on other nontarget species.
Potential for adverse effects on pet dogs or other domestic animals that might consume the baits.	Low risk; Possible benefit from improving immunity to rabies.	Low risk; states would likely still conduct ORV programs. Increased risk of rabies for unvaccinated animals without federal assistance.	No risk of adverse effects from consuming ORV baits.	Low risk (similar risk as Alt. 1); increased risk of rabies for unvaccinated animals if reduced monitoring and surveillance reduces effectiveness of ORV programs.	Low risk; Possible benefit from improving immunity to rabies.
Potential for the recombined V-RG virus to "revert to virulence" and result in a virus that could cause disease in humans or animals.	Very low risk.	Less risk than Alt. 1; states would likely still conduct ORV programs.	No risk.	Low risk (similar risk as Alt. 1).	Very low risk.
Potential for the V-RG virus to recombine with other viruses in the wild to form new viruses that could cause disease in humans or animals.	Very low risk.	Less risk than Alt. 1; states would likely still conduct ORV programs.	No risk.	Low risk (similar risk as Alt. 1).	Very low risk.
Potential for aerially dropped baits to strike and injure people or domestic animals.	Low risk.	Less risk than Alt. 1; states would likely still conduct ORV programs.	No risk.	Low risk (similar risk as Alt. 1).	Low risk.

Table 1: Issues/Impacts/Alternatives/Comparison

Cost of the program in comparison to perceived benefits.	Expected benefits exceed costs of program.	Cost of adverse effects from rabies spread would be much greater than cost savings from not having federal assistance.	Expected benefits unlikely to exceed costs of program.	Expected benefits exceed costs of program (similar to Alt. 1); benefits may not exceed costs if reduced monitoring and surveillance reduces effectiveness of ORV programs.	Expected benefits exceed costs of program.
Humaneness of methods used to collect wild animal specimens critical for timely program evaluation or to reduce local populations of target species under state contingency plans	Capture and handling of raccoons would be viewed by some persons as inhumane. Methods viewed as inhumane by some persons would be used to take gray fox and coyotes in Texas, but many animals saved from suffering and death due to rabies.	Probably less impact on this issue than Alt. 1; states likely to still conduct ORV programs with monitoring and surveillance and contingency plan implementation, but at a smaller scale without federal assistance; more animals likely to die of rabies if lack of federal assistance reduces effectiveness of ORV programs.	Capture and handling of target species would be viewed by some persons as inhumane. Fewer gray fox and coyotes would be taken in Texas using lethal methods, however, so this alternative would be viewed as more humane than Alt. 1.	This Alt. would be viewed as more humane than Alt. 1; states likely to still conduct monitoring and surveillance and contingency plan implementation, but at a smaller scale without federal assistance; more animals likely to die of rabies if reduced monitoring and surveillance reduces effectiveness of ORV programs.	Capture and handling of raccoons would be viewed by some persons as inhumane. Methods viewed as inhumane by some persons would be used to take gray fox and coyotes in Texas, but many animals saved from suffering and death due to rabies.

Cumulative Impacts

No significant cumulative environmental impacts are expected from any alternative, with the possible exception of Alternative 2 - No Action, which might lead to increased human exposures and domestic and wild animal rabies cases across much of the U.S. Although some persons will likely remain opposed to the use of genetically engineered vaccines or the use of the vaccinia pox virus as a component of the ORV, and some will remain opposed to the lethal removal of raccoons, gray fox, or coyotes for monitoring purposes or for implementation of contingency rabies management plans, the analysis in the EA indicates that ORV use and such lethal removals will not result in significant risk of cumulative adverse impacts on the quality of the human environment.

Finding of No Significant Impact

The analysis in the EA and this Decision/FONSI indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of implementing the proposed action (Alternative 5). I agree with this conclusion and, therefore, find that an EIS need not be prepared. As defined in 40 CFR §1508.27, significance is determined by examining the following criteria:

1. **Impacts that may be both beneficial and adverse.** The ORV vaccine and bait that is used has been found safe for raccoons, gray foxes, coyotes, and other animal species; has a low risk of causing adverse affects to humans; is readily consumed by target animal species; and does not cause bioaccumulation in the environment. A limited number of baits are distributed one or two times per year, thereby minimizing the potential for persons to be exposed to an ORV bait or to bait distributing equipment. The TVR type of contingency action involves the use of a parenteral (injectable) vaccine on the specific animal that is trapped. Injectable vaccines can be used "off label" under the direction of veterinarians to vaccinate healthy wildlife. Thus, vaccinated animals should exhibit no effect other than becoming immunized against rabies. In addition, positive health benefits to the public and target and nontarget animal populations likely occur through decreased risk of exposure to rabid animals.

2. **Degree of effect on public health or safety.** The proposed action poses minimal adverse impact to public health and safety. Of more than 66.3 million baits distributed since 1990, few (10) minor injuries and no significant injuries to any member of the public are known to have resulted from ORV programs. Adverse

health effects from vaccinia associated with ORV have been minimal with no significant long-term effects expected. The TVR type of contingency action involves the use of a parenteral (injectable) vaccine on the specific animal that is trapped. Therefore, the general public would not be exposed to this type of vaccine. Positive health benefits to the public likely occur through decreased risk of exposure to rabid animals.

3. **Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.** As described in the EA, no effects to natural or cultural resources were identified for the preferred alternative. There are no prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas affected.

4. **Degree to which effects on the quality of the human environment are likely to be highly controversial.** The effects on the quality of the human environment are not highly controversial. Although there is some opposition to certain methods used to collect animal specimens for monitoring purposes and contingency actions, their use under the proposed action is not highly controversial in terms of size, nature, or effect.

5. **Degree to which the possible effects on the quality of the human environment are highly uncertain or involve unique or unknown risks.** Based on the analysis documented in the EA and this Decision/FONSI, the effects of involvement by APHIS-WS in ORV programs, including contingency actions, on the human environment is not significant. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks.

6. **Degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.** The proposed action does not establish a precedent for any future action with significant effects.

7. **Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.** No significant cumulative effects on the quality of the human environment were identified through this assessment.

8. **Degree to which the action may adversely affect districts, sites, highways, structures, or objects listed on National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.** The proposed activities do not affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor are they likely to cause any loss or destruction of significant scientific, cultural, or historical resources.

9. **Degree to which the action may adversely affect an endangered or threatened species or its critical habitat.** An evaluation of the proposed action and its effects on T&E species concluded that no significant adverse effects will occur to such species, nor will there be any impact on critical habitat for any listed species. Since ORV program inception, significant adverse effects have not occurred to such species or their habitat. In fact, sensitive species may benefit from a reduced risk of encountering a rabid animal and dying from rabies.

10. **Whether the action threatens a violation of federal, state, or local environmental protection law.** The proposed action is in compliance with all federal, state, and local laws imposed for the protection of the environment.

Decision

I have carefully reviewed the EA, supplemental EAs, associated Decision/FONSIs, this Decision/FONSI, and the input resulting from the public involvement process. I believe the issues and objectives identified in the EA would be best addressed through implementation of Alternative 5 (Proposed Action), a combination of Alternatives 1 and 3. Alternative 5 is therefore selected because it offers the greatest flexibility in achieving effectiveness while minimizing cumulative adverse impacts on the quality of the human environment with respect to the issues raised for consideration in this process. The APHIS-WS program will implement the proposed action as described in this Decision/FONSI and in compliance with all applicable mitigation measures listed as components of standard operating procedures in Chapter 3 of the EA. Unless new substantial issues bearing on the effects of the proposed expansion of the oral rabies vaccination program are brought to our attention, this decision will take effect 30 days after publication of a notice of its availability in the Federal Register.

For additional information regarding this decision, please contact Dennis Slate, National Rabies Program Coordinator, APHIS-Wildlife Services, 59 Chenell Drive, Suite 7, Concord, NH 03301-8548; phone (603) 223-9623.

for David S. Reinhold April 10, 2007

William Clay, Deputy Administrator Date
APHIS-WS

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